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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,186	04/04/2005	Kazuhiro Saito	074129-0519	5576

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EXAMINER	
TELLER, ROY R	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
02/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,186	SAITO ET AL.	
	Examiner	Art Unit	
	ROY TELLER	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-18,20,22,25 and 27-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-18,20,22,25 and 27-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/30/08 has been entered.

Claims 16-18, 20, 22, 25 and 27-30 are under examination.

Response to Amendments/ Arguments

Applicant's arguments filed 12/30/08 are acknowledged and have been fully considered. Any rejection and /or objection not specifically addressed is herein withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-18, 20, 22, 25 and 27-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7, 19, 20, 23, and 27 of copending Application No.10/498,215. Although the conflicting claims are not identical, they are not patentably distinct from each other because the sustained release composition contains the same lactic acid polymer molecular weight averages, same peptide equivalent and is used to prevent or treat the same diseases .

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments were carefully considered but were not found persuasive. Applicant requests that the provisional obviousness-type double patenting rejection be held in abeyance because the '215 application is undergoing examination. However, the examiner requests a terminal disclaimer be filed at this time.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-18 , 20, 22, 25 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al (USPN 6,113,943) in view of Hutchinson (USPN 5,889,110).

The instant invention is drawn to a sustained release preparation comprising a combination of first microcapsules which release a GnRH agonist (or LHRH) for 5 months or longer and second microcapsules which release a GnRH agonist (or LHRH) for a term shorter than 5 months.

Such compounds having GnRH activity include, specifically, leuprorelin, buserelin and goserelin, see, i.e, for example, specification, page 2, lines 2-4.

Okada teaches a sustained release preparation comprising a polymer of lactic acid having an average molecular weight of about 25,000 to about 60,000 and a physiologically active peptide, wherein the peptide is leuprorelin, leuprorelin acetate, buserelin or goserelin, and which releases the physiologically active substance over a period of at least five months, see, ie., abstract, column 1-2, claims 1 and 11. Okada discloses when the physiologically active substance is leuprorelin or leuprorelin acetate, a sustained release preparation is useful for diseases such as prostatic cancer and breast cancer, see, i.e., for example, column 20.

Okada does not teach a short term use of the sustained release preparation.

Hutchinson teaches extended release pharmaceutical compositions, which suitable pharmacologically active peptides such as LHRH, leuprorelin, buserelin, and goserelin, see, i.e., for example, abstract, column 2, claim 4 and 14, . Hutchinson discloses experiments for the release of goserelin over relatively short periods of time of 5-7 weeks, see, i.e., for example, column 26. Huttchinson teaches a lactide/glycolide co-polymer having a weight average molecular weight of about 15,000 Da, see, i.e., for example, column 30.

Based upon the beneficial overall teachings provided by Okada with respect to Hutchinson , Hutchinson discloses similar formulations can be manufactured using, in place of goserelin, either leuprorelin or buserelin and continuous release over a relatively long period of time of up to 6 months, see, i.e, for example column 25 and 22. Okada discloses the dose of the sustained release preparation per administration for one month in terms of a physiologically active range, see, i.e, for example, column 20.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments were carefully considered but were not found persuasive. Applicant contends that the cited references do not teach a blood concentration of the GnRH agonist within one week after administration is about 2 ng/ml or higher. Further, applicant contends that the cited prior art does not teach or suggest a combination of two kinds of microcapsules of polymers having different weight average molecular weights to produce a sustained release preparation. However, the examiner contends that this intended *in vivo* functional effect would be intrinsic to (and/or obvious over) the sustained release product reasonably suggested by the cited references (as discussed above). Further, the adjustment with respect to the *in vivo* blood concentration level for such a sustained release preparation would have been obvious to the skilled artisan within the pharmaceutical art (including within the

sustained release pharmaceutical art). Further, the examiner contends that Huttchinson teaches a lactide/glycolide co-polymer having a weight average molecular weight of about 15,000 Da and Okada teaches a sustained release preparation comprising a polymer of lactic acid having an average molecular weight of about 25,000 to about 60,000 and a physiologically active peptide.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RT
1654
2/17/09

/Christopher R. Tate/
Primary Examiner, Art Unit 1655